K093393

SAFETY AND EFFECTIVENESS SUMMARY
Summit Doppler Systems, Inc.
LifeDop 300ABI

Name and Address:	Summit Doppler Systems, Inc. 4680 Table Mountain Dr. #150 Golden, CO 80403 Phone: (303) 423-7572 Fax: (303) 431-5994
Contact:	Ken Jarrell – President
Preparation Date:	October 23, 2009
Device Name:	LifeDop 300ABI
Common Name:	Peripheral Vascular Doppler

DEC 2 4 2009

Classification:	Class II per:	FR Number	Product Code
	Non-Fetal, Ultrasound Monitor	892.1540	JAF

Indications for Use:

Vascular (5.0 and 8.0 MHz Probes)
This product will be used to detect blood flow in veins and arteries for assisting in the detection of peripheral vascular disease.

Description:

The LifeDop is a hand-held, battery powered, audio Doppler device used for blood flow detection in veins and arteries. The product includes two interchangeable ultrasound transducer probes and user replaceable batteries. The user interface includes an on/off button, volume control, 12 button keypad for entering pressure data and printing, single 2-1/4" speaker, and LCD display for displaying data, battery and waveform information. The product is housed in custom injection molded housings. Patient contact materials are ABS and Ploycarbonate injection molded plastic and hypoallergenic aqueous gel used for ultrasound transmission.

Substantial Equivalence:

Summit Doppler Systems
Golden, CO
LifeDop Doppler Ultrasound System
K024197, Cleared 1/3/03

Technologies Summary:

Doppler ultrasound technology is the same as substantially equivalent device shown above. There is no change in the intended use of the device.

Clinical Testing:

None provided

Conclusion:

Based on comparisons of device features, materials, intended use and performance, the LifeDop 300ABI is shown to be substantially equivalent to the commercially available and legally marketed device indicated above.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

Mr. Ken Jarrell
President
Summit Doppler Systems, Inc.
4680 Table Mountain Dr. #150
GOLDEN CO 80403

DEC 24 2009

Re: K093393
Trade/Device Name: LifeDop 300ABI
Regulation Number: 21 CFR 892.1540
Regulation Name: Nonfetal ultrasonic monitor
Regulatory Class: II
Product Code: JAF
Dated: October 23, 2009
Received: October 30, 2009

Dear Mr. Jarrell:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

This determination of substantial equivalence applies to the following transducers intended for use with the LifeDop 300ABI, as described in your premarket notification:

Transducer Model Number

5.0BD MHz CW
8.0BD MHz CW

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus permits your device to proceed to market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

If you have any questions regarding the content of this letter, please contact Shahram Vaezy at (301) 796-6242.

Sincerely yours,

Janine M. Morris
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure(s)

Attachment C – Indication for Use

Indications for Use

510(k) Number (if known): K093393

Device Name: LifeDop 300ABI

Indications For Use: This product will be used to detect blood flow in veins and arteries for assisting in the detection of peripheral vascular disease.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K093393

K093393 ADDENDUM
1/1

Diagnostic Ultrasound Indications for Use Form

LifeDop 300ABI peripheral vascular system with either 5.0BD MHz CW or 8.0BD MHz CW
Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal										
Abdominal										
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric										
Small Organ (specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethal										
Intravascular										
Peripheral Vascular					P					
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (specify)										

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments: 5.0 MHz Bi-Directional Peripheral Vascular Probe – K063600, 12/19/06

8.0 MHz Bi-Directional Peripheral Vascular Probe – K063600, 12/19/06

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CRF 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K093393

Diagnostic Ultrasound Indications for Use Form

5.0BD MHz CW Peripheral Vascular Probe
Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal										
Abdominal										
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric										
Small Organ (specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethal										
Intravascular										
Peripheral Vascular					P					
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (specify)										

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments: The above is for 5.0 MHz Bi-Directional Peripheral Vascular Probe
Previously submitted and cleared on K063600, 12/19/06

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CRF 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K093393

Diagnostic Ultrasound Indications for Use Form

8.0BD MHz CW Peripheral Vascular Probe

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal										
Abdominal										
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric										
Small Organ (specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethal										
Intravascular										
Peripheral Vascular					P					
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (specify)										

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments: The above is for 8.0 MHz Bi-Directional Peripheral Vascular Probe

Previously submitted and cleared on K063600, 12/19/06

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CRF 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K093393